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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,408	08/05/2003	Jong-Gu Park	57354-08USA	8424

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,408	PARK ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,18 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,18 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/07 has been entered.

Applicant's RCE requests reconsideration of the filing of 12/14/06, and hence, such filing is now made of record, and addressed as if filed at the time of RCE, 12/17/07.

Claims 2, 3, 9-17, 19, and 20 are cancelled.

Claims 1 and 18 are amended.

Claims 21-24 are newly added.

Claims 1, 4-8, 18, and 21-24 are presently pending and considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claims 2, 3, 9-17, 19, and 20, all rejections and/or objections to such claims are moot, and thus, are withdrawn.

Note: Arguments to possession

Applicant's arguments to their possession and already-considered subject matter after-final, filed 12/1707 are moot, as Applicant has filed an RCE, and hence, such arguments are not addressed.

Claim Rejections - 35 USC § 112 - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 1, 4-8, and 18, under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for its full scope, are withdrawn, in light of the following scope of enablement.

Claims 1, 4-8, 18, and 21-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Methods of treating glomerulosclerosis and progression of proteinurea in rodents, comprising delivery of a nucleic acid encoding IL-10 or allogeneic cells transformed to secrete IL-10, to the kidney, wherein cells of the kidney are transformed and secrete IL-10 in the case of nucleic acid transformations of kidney cells, thereby ameliorating autoimmune responses and ameliorating the progression of proteinuria or glomerulosclerosis, does not reasonably provide enablement for the breadth of administrations, lack of secretion of IL-10, species and *ex vivo* therapies with xenogenic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's claims encompass treating any animal with kidneys, and ex vivo gene therapies with any cell type, as well non-secretion of IL-10.

Such is broad the breadth of each of these genera, and the breadth of such is not such that the Artisan would reasonably predict that the various methods are efficacious for their breadth.

The core of the enablement is based upon the treatment of any species. As is of record, it was recognized at the time of invention that Applicant's experiments, carried out in rodent models, is not reasonably predictive of larger animals, including humans, which is taught in the specification (confluence of SPECIFICATION). To wit, as has been stated (e.g., Official Action of 11/21/05), Tomasoni, et al. (2004) Current Gene Therapy, 4: 115-22, provides a recent review of such therapies. First, Tomasoni recognizes the barriers which a vector must traverse to target the specific tissues, which must be assessed in order to use them experimentally (p. 115, col. 1, paragraph 1), thereby recognizing the various aspects of gene therapy (vector targeting to deliver gene to enough cells and thereby express enough protein). Moreover, toxicity, immunogenicity, and efficiency are other aspects which may preclude any particular vector use (Id., paragraph 2). Further, each vector type contains various problems and advantages, and therefore, any particular vector is not reasonably predicted to produce enough of an effect for a long enough time. Lastly, Tomasoni concludes with a clear indication that gene therapy for renal disease (in humans) is a long way from being reasonably predictable. To wit, gene delivery is the major hurdle, and while looking feasible, studies are needed to establish if the present studies carried out in rodents will extrapolate to larger animals (p. 120, col. 2, paragraph 2). Moreover, identification of the causes of the various disorders are still required to identify the defective genes and be able to target them (Id.). Concluding, Tomasoni states "Much basic research is needed before gene transfer can be added to the therapeutic armamentarium for human kidney diseases." (Id.).

Hence, Tomasoni, writing an Artisan, recognizes that the rodent animal models, even when they are efficacious, require further testing in other animals to make the therapies reasonably predictable for humans. Moreover, Tomasoni recognizes that any particular gene

delivery method encompassed will require confirmation to determine that enough cells are transformed, express and screcrete enough protein, and do so for a long enough time to have a therapeutic effect.

Applicant's own post filing art, disclosing the same basic disclosure as the present Application, also echos the problems noted in Tomasoni (Choi, et al. (2003) Gene Therapy, 10: 559-68, p. 565, paragraph bridging columns), by stating that it would be useful to determine if the same experiments can be extrapolated to other animals. Hence, it would appear that Applicant also recognizes the lack of reasonable predictability in the Art.

With regard to the secretion of IL-10, it is necessarily required to be secreted to act and have the effects, if not, it would just be a protein in a cell in the kidney, And not an anti-inflammatory agent.

With regard to the ex vivo therapy, it is well known in the Art that xenogenic cells would simply increase immune reactions, and simply therefore exacerbate the immunological responses which are the causes of the majority of disorders in the presently claimed embodiments.

Also, with regard to ex vivo therapy, it is noted that there existed several methods to deliver cells to the kidneys, and because all that is required is the secretion of IL-10 from these cells to have the same effect as the gene transfer methods, it is difficult to argue that ex vivo approaches are not sufficiently enabled (e.g., Kitamura (2000) Journal of the American Society of Nephrology, 11: S154-58, e.g., p. S154, paragraph 1).'

Hence, the Artisan would have to experiment to determine if (1) these therapies would work in other animals than rodents, (2) whether xenogenic cells would not produced increased immune reactions which would exacerbate rather than ameliorate the problems, and (3) if non-

secreted IL-10 would work, which amounts to inventing the breadth of Applicant's claimed subject matter for Applicant, and therefore, is considered undue.

Hence, Applicant's claims are considered to be non-enabled for their fully claimed scope.

Response to Argument - enablement

Applicant's argument of 12/17/07 (filed 12/14/06) has been fully considered but is not found persuasive.

Applicant argues that their model enables the breadth claimed, citing their experimental data and results (pp. 6-7).

Such is not persuasive for the breadth claimed, for reasons of record and the resasons given above.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Acting Examiner of Art Unit 1633